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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,605	12/22/2000	Gary C. Starling	DB13NP; 30436.43USU1	1201

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EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 02/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,605

Applicant(s)

STARLING ET AL.

Examiner

Maheer M. Haddad

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-52 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Fax Transmission Restriction Election.

DETAILED ACTION

Sequence Compliance

1. The instant application appears to be in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

Restriction Requirement

2. Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. The following is noted:

It is not readily apparent how SEQ ID NOS: 7-42, read on APEX-1, APEX-2 and APEX-3. In the absence of any recitation in the claims or any direction in the specification to the contrary, the restriction of the SEQ ID NOS: 7-42 is set forth as separate groups. It appears that SEQ ID NOS: 7-42 possess different structure and distinct nucleic acid molecules, since SEQ ID NOS: 7-42 are structurally distinct, *the restriction has been set forth for each as separate groups, irrespective of the format of the claims.*

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- I. Claims 1-5, 15-26, 42-43 and 50, drawn to an isolated nucleotide sequences of SEQ ID NO: 1 encoding a polypeptide; vectors, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- II. Claims 6-10, 15-26, 42-43 and 50, drawn to an isolated nucleotide sequences of SEQ ID NO: 2 encoding a polypeptide; vectors, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- III. Claims 11-26, 42-43 and 50, drawn to an isolated nucleotide sequences of SEQ ID NO: 3 encoding a polypeptide; vectors, host cells, and methods of producing the polypeptide, classified in Class 536, subclass 23.5; Class 435, subclasses 69.1, 455, 252.3, and 320.1.
- IV. Claims 27-28, and 44-46, and 51, drawn to a protein comprising SEQ ID NO: 4, fragments thereof, fragments having APEX-1 activity and soluble APEX-1 protein; classified in Class 530, subclasses 350.
- V. Claims 27, 29, 44-46 and 51, drawn to a protein comprising SEQ ID NO: 5, fragments thereof, fragments having APEX-2 activity and soluble APEX-2 protein; classified in Class 530, subclasses 350.
- VI. Claims 30, 44-46, and 51, drawn to a protein comprising SEQ ID NO: 6, fragments thereof, fragments having APEX-3 activity, and soluble APEX-3 protein; classified in Class 530, subclasses 350.
- VII. Claims 31-41 and 52, drawn to an antibody against APEX-1, antibody conjugates, and pharmaceutical compositions thereof; classified in Class 530, subclass 387.3, and 391.1; Class 424, subclass 133.1.
- VIII. Claims 31-41 and 52, drawn to an antibody against APEX-2, antibody conjugates, and pharmaceutical compositions thereof; classified in Class 530, subclass 387.3, and 391.1; Class 424, subclass 133.1.
- IX. Claims 31-41 and 52, drawn to an antibody against APEX-3, antibody conjugates, and pharmaceutical compositions thereof; classified in Class 530, subclass 387.3, and 391.1; Class 424, subclass 133.1.
- X. Claims 47-49, drawn to a method of identifying a molecule using antibody against APEX 1; classified in Class 435, subclass 7.1.

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- XI. Claims 47-49, drawn to a method of identifying a molecule using antibody against APEX-2; classified in Class 453, subclass 7.1.
 - XII. Claims 47-49, drawn to a method of identifying a molecule using antibody against APEX-3; classified in Class 335, subclass 7.1.
 - XIII-XLVII. Claim 50, drawn to a nucleic acid molecule having SEQ ID NOS: 7-42, classified in Class 536, subclass 23.5.
5. Groups I- III, IV-VI, VII-IX and XIII-XLVII are different products. Nucleic acids, polypeptides, and antibodies to the polypeptides differ with respect to their structures and physicochemical properties; therefore each product is patentably distinct.
6. Groups I-III and IV-VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product, the protein can be made using an amino acid synthesizer.
7. Groups VII-IX and X-XII are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group VII-IX can be used for affinity purification, in addition to the methods of treating and detecting recited.
8. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to the following patentably distinct species of the claimed Inventions I-III and VII-IX: wherein the detectable marker is:

- A) a radioisotope,
- B) a fluorescent compound,
- C) a bioluminescent compound,
- D) a chemiluminescent compound,
- E) a metal chelator, or
- F) an enzyme.

These species are distinct because their structures and mode of actions are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. This application contains claims directed to the following patentably distinct species of the claimed Invention X-XII: wherein the sample is:

- A) brain,
- B) bone marrow,
- C) heart,
- D) kidney,
- E) liver,
- F) lung,
- G) lymph node,
- H) pancreas,
- I) placenta,
- J) skeletal muscle,
- K) thymus,
- L) blood,
- M) urine,
- N) plasma, or
- O) serum.

These species are distinct because their structures and mode of actions are different.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

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11. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

12. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
February 4, 2002

Phillip Gambel
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2/7/02